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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/668,012	09/22/2003	Simon Furnish	12258-035001	1983
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FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			EXAMINER JAWORSKI, FRANCIS J	
			ART UNIT 3737	PAPER NUMBER

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/668,012	FURNISH ET AL.
	Examiner	Art Unit
	Jaworski Francis J.	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 September 2004.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 - 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 - 21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 September 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09182004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 20 is objected to because of the following informalities: in line 3 "director" should read -- redirector --. Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[Parenthesized numerals pertain to the specific claim or claims being rejected in the immediately preceding rejection argument.]

I. Transponder/Position Sensing Arguments

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jongeling et al (WO 90/13253) or in the alternative under 35 USC 103(a) as obvious over Edwards et al (US5681277) and Edwards et al (US5964727). Neither Jongeling et al nor the Edwards et al patents have anything to do with dual mode optical analysis and ultrasound imaging however under this interpretation neither does the base claim 1 language. That is, either an optical or ultrasound detection component may serve in a position-sensing function in an intravascular device which uses the other modality, ultrasound or optics for a therapeutic or diagnostic purpose akin to applicants. The preamble does not limit between position encoding/transponding or diagnosis or therapy nor does the language associated with components of the optic or ultrasound modalities. Therefore:

Jongeling teaches an intra-arterial ultrasound scanning catheter with an optical rotary encoder comprising:

a sheath (catheter tube 1 or cap 2) with distal and proximal ends,

a first optical fiber waveguide 4 extending therealong so as to bi-directionally carry optic radiation,

a first beam re-director (reflectivity disc 5 acting to reflect its rotating markings (see page 7 lines 14-25),

an optical detector (inherently present in the computer-controlled processing which registers the scanlines properly according to the reflected rotational encodings),

an ultrasound transducer 10 configured to couple energy between the probe and cap and intervening blood, and

transducer signal wires 11 and 12 extending along the interior of the sheath 1.

Edwards et al (US5681277) is directed to providing optical viewing for a stylet catheter and also associates the catheter with ultrasound position sensing. Edwards et al (US 5964727) notes that stylet catheters may be used vascularly and specifically defines what ultrasound position sensing or transponding entails. In combination either may serve as base reference to describe:

An intravascular stylet catheter ('727 col. 13 line 29 – 34 establishes that this type of catheter is intravascularly usable) comprising:

a catheter sheath;

A first optical waveguide 114, 119 extending along the sheath and carrying illumination to the forward tip,

A beam re-director (see Figs.; saddle-tip serves this lateralizing function),

An optical detector lens 22 and connector 24 (see elements 88, 90 regarding focus detection),

An ultrasound position sensing transducer('277 col. 3 lines 22 – 28),

And wiring extending within the stylet catheter sheath for enabling the tip ultrasound transducer to act as an acitive transponder in lieu of an echocontrast tip material and contribute to spatial registry of the catheter tip (in conjunction for example with a surface ultrasound imager) on an ultrasound image ('727 col. 9 lines 1 – 7).
(Claim 1).

Hence the Examiner is arguing that absent any structural definition limiting the optical and ultrasound portions to diagnostic application, each modality can serve for position registry in an intravascular device using the other modality alone for lesion diagnosis.

II. Endoscopic Analogy Argument

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adler (US6692430) in view of Suwaki et al (US4375818).

In Adler the technology improvement is directed to distal incorporation of infrared imaging source(s) 3 and sensor(s) 8, onto a catheter for inter alia characterizing intravascular plaque. Adler notes that intravascular optical plaque viewing as well as ultrasound plaque viewing were well-known and separately

practiced., see col. 2 lines 1 – 44 and col. 2 lines 45 – 53. Since Suwaki et al noted early on that when an ultrasound transducer 12 is located on an internal probe next to a radially re-directed optical viewing fiber bundle 13 including an illumination source and a detection eyepiece in its system, the advantage could be had that the visual observation could pinpoint the subsurface ultrasound inspection site and vice-versa, see col. 2 lines 27 – 55. It would therefore have been obvious to do so in the angioscope since separate optical intravascular surface viewing and ultrasound subsurface scanning were analogously known to be complementary in plaque identification in the intravascular case. Suwaki et al additionally recognized intravascular catheters as being analogous to ultrasound imaging purposes, see Col. 2 lines 16 – 21.

Hence the Examiner is arguing that combined ultrasound and optic viewing was well-known in association with internal probes and this feature would readily transfer to intravascular probes.

III Opto-acoustic Arguments

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Celliers et al (US6022309) and Melcher et al (US4504727) which is incorporated by reference therein, or in the alternative under 35 USC 103(a) as obvious thereover.

Celliers et al is directed to opto-acoustic lysis of intra-arterial clots wherein a laser source delivers optic radiation for conversion to low frequency ultrasound at the catheter tip and as such teaches:

An intravascular catheter comprising:
a sheath of catheter 14 (Face figure),
a first optical waveguide 10 which may be a single fiber or a fiber bundle (col. 5
line 65) configured to carry laser radiation to the distal end, and
a first beam re-director distally disposed in optical communication with the
waveguide (the end-surface of 10 may be concave or convex in order to re-direct the
laser irradiation at the distal end, see Figs. 4A-4B, or the fiber bundle may be
structured to effect same, see col. 5 line 55 – col. 6 line11), and

[Celliers et al contains (i) the instruction to incorporate the technique of Melcher
et al in a fashion interpretable as an acoustic i.e. ultrasound feedback technique (see
Celliers et al col. 2 lines 38 – 40) and col. 7 lines 62-65) and (ii) to use an imaging
technique where the vibrating device tip is the point source emitter (see Celliers et al
col.6 lines 37 – 42) and (iii) to use a conventional echographic ultrasound or optical or
photoacoustic imaging device therewith, see col. 7 lines 58-62.]

Under (i) Melcher et al in and of itself then teaches that for photoacoustic control
of laser industrial drilling may be governed by the composite of a feedback channel "a"
and its governance of a feedback channel "b" termed a BFPS or Beam Focussing and
Photoacoustic Sensing system. Specifically then Celliers et al by incorporation is
further teaching:]

An optical detector 19, 22, 52 of Melcher which captures a partial reflection of the
laser radiation onto an infrared sensor portion 52 to provide channel "a", and

An ultrasound transducer 59 to detect the photoacoustically generated ultrasound from the waveguide as redirected at the tip and provide same out of the catheter 14 by a wire 56.

In the alternative Cellier et al I is argued to effectively teach that in addition to control feedback such as by Melcher et al - note that the Melcher et al IBFPS system is not an imager but a feedback control which provides a wavetrace signature - one might incorporate an imaging function either by using the laser tip location as the ultrasound transmitter point source (suggestion ii) and/or by incorporating a conventional catheter-tip imaging system with or without using the source (suggestion iii). (Claim 1).

Hence the Examiner is arguing that an opto-acoustic intravascular catheter as represented by Cellier et al is readable against claim 1 either by its opto-ultrasonic composite feedback control loop or by its incorporation of conventional catheter tip ultrasound imaging alongside such control.

IV. Core Arguments (Catheter-based Optical Arterial Plaque Analysis with Ultrasound Characterizing Visualization)

(a) Casscells et al '075 v Eberle et al alone or v Casscells et '071 - based

Claims 1 - 11, 15 – 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over (a) Casscells et al (US5,935,075) in view of Eberle et al (US5167233) alone or further in view of Casscells et al (US6615071).

Casscells et al is directed to an intra-arterial plaque characterizing catheter with suggestion to incorporate ultrasound imaging therewith. O'Donnell et al represents an IVUS (Intravascular Ultrasound) imaging and plaque-treating catheter whose transducer array is operational within a balloon tip, see Fig. 1B. The Cascells et al patent teaches:

An intravascular probe comprising:

an optical fiber waveguide (50 and reference 60) extending along the sheath of catheter 10 (see col. 12 lines 48-52 identifying this not-shown sheath),

a first beam re-director mirror for directing the beam of 50 towards the artery wall plaque (col. 9 lines 27 – 37),

an optical detector in the form of a filtered radiometer coupled to a photo-electric digitizer (col. 10 lines 11 – 46),

and suggestion in the Abstract to incorporate an ultrasound imaging device into the catheter, whereupon

[Note that the Pre-grant Publication US2003/0236443 to Cespedes et al (used in additional rejection (b), see below) in its para [0013] disputes that such a device interpretation is correct. However the Examiner interprets the Casscells et al '075 patent disclosure as solely referring to IVUS use as a next-best prior art plaque characterizing technology (see col. 3 lines 17 – 28) and the Abstract language " a

catheter with an infrared detector (with or without ultrasound) *employed at its tip* " as lending to the interpretation that a dual optic and ultrasound catheter device is being invoked. Hence whereas the later Casscells et al patent confirms this fact, see col. 22 lines 22 – 30 referring to the Eberle et al assignee Endosonics, the earlier Casscells et al is sufficient for this interpretation.].

it would have been obvious in view of Eberle et al to provide an IVUS array transducer 44 with electrical communicating wire 62 extending along the catheter sheath 28 since this catheter is adaptable to image from inside a catheter tip balloon placed by central guidewire such as found in Casscells et al and admits of multi-lumen usage flexibility as per Figs. 7 necessary to support the combined optical fiber and ultrasound and guidewire components. (Claim 1).

Since Cascells et al proposes additional fibers (beyond the reference fiber 60 required for infrared measurement standardization) to support measurement at multiple site positions, see col. 9 lines 9 – 26, these additional sets would include a first as well as a second or further optical waveguide and a first as well as a second or further beam re-director mirror as described above. (Claims 2 – 3, 5 – 6, 10 - 11).

A second or further infrared optical source would be necessary in order to not confound the standardizations associated with respective reference fibers assigned to the infrared sensing fibers at the multiple sites. (Claims 4, 8 - 9).

The multi-wavelength radiometer and aforementioned photoelectric digitizer serve as detector for the first and additional fibers, see col. 10 lines 6 - 10 and lines 41 – 46.(Claim 7).

At least the balloon portion of Casscells et al is infrared-transparent, see col. 13 line 57 – col. 14 line 12. (Claim 15).

Since the infrared results would be spatially co-registered with the ultrasound (else the dual characterization i.e. the augmenting of ultrasound information with IR information would have no validity) this mandates that the ultrasound array element radial directionality be fixed with the fiber(s) radial re-direction in Casscells et al yet flexible axially so as to be capable of the placement bend radius shown in Eberle et al Fig. 1b. (Claims 16 – 17).

In the multiple fiber/multiple measurement site case contemplated in Casscells et al, the proposed tip transducer array would only be present at one site (unless moved for example by the mechanism of Eberle et al Fig. 6a). (Claim 19).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Casscells et al '075 in view of Eberle et al alone or further in view of Casscells et al '071 as applied to claim 5 above, and further in view of Adler (US6692430).

The former reference pair are applied as above. Adler is characterized as above, namely as an IR plaque-characterizing intravascular catheter which has optical fiber waveguides and re-directing means, with additional note that Adler specifically identifies Eberle et al in Col. 2 lines 52 – 53 as related to the plaque characterization technology nexus. Since Adler notes the equivalence of a reflecting mirror and a prism in

as a re-directing element, see col. 3 lines 57 – 58, it would have been obvious to substitute a prism for the reflector described in Casscells et al. (Claim 12).

Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casscells et al '075 in view of Eberle et al alone or further in view of Casscells et al '071 as applied to claim 5 above, and further in view of Suwaki et al.. Whereas the former are silent as to bend-redirection of fibers, it would have been obvious in view of the latter to bend a fiber or fiber bundle 13 at the internal instrument tip since like the ultrasound it must be radially re-directed to investigate the body lumen or artery wall surroundment. (Claim 13).

Suwaki et al evidences that the two modalities should be present at the same approximate axial location along the longitudinal axis of the internal device since they are viewing the same pathological site. (Claim 18).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Casscells et al '075 in view of Eberle et al alone or further in view of Casscells et al '071 as applied to claim 5 above, and further in view of Melcher et al. Whereas the former are silent as to the specific nature of the ultrasound transducer(s) used, it would have been obvious in view of the latter col. 4 lines 37 – 41 to use a piezoelectric transducer since this is the standard acousto-electronic transduction material category. (Claim 14).

Claims 20 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casscells et al '075 in view of Eberle et al alone or further in view of Casscells et al '071 as applied to claim 5 above, and further in view of Winston (US5916210)..

The former are applied as above, however they are silent as to (1) the co-rotation of the beam (re)director and transducer and to (2) the setting of concurrent circumferential spacings for waveguides, redirectors and transducers..

It would however have been obvious in view of Winston Figs. 4-5, 12, 17 to co-rotate an ultrasound transducer and an optically re-directed element in a containment sheath since in the analogous setting of an intra-arterial catheter providing optical (laser ablation) therapy and ultrasound intra-arterial imaging it was known to co-rotate same for complete radial position coverage. (Claim 20).

Alternatively, it would have been obvious to provide an ultrasound radial phased array 108 in association with multiple circumferentially placed fibers 30 and redirector(s) 104 since this provides complete radial position coverage without need for rotation. (Claim 21).

(b) Cespedes et al – based

Claims 1 – 10, 13, 16 - 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Cespedas et al (US2003/0236443, of record in the IDS filed 09-14-2004.)

Céspedas et al is directed to an intra-arterial catheter system which incorporates infrared thermography and ultrasound distal tip imaging. In consideration of the two fiberoptic embodiments of interest, embodiment first Fig. 7 and attendant paras [0107 – 0111]. And embodiment second Figs 8a – 8b and paras [0112 – 0115] the anticipatory reading is:

an intravascular probe (180 or 197, 200) comprising:

first waveguide or plural waveguides (187 in all cases) extending within the catheter sheath,

first beam or plural beam radial re-directors (distal bends in the fibers to re-direct them radially),

proximally coupled optical thermography detectors (not shown),

a rotating (185) ultrasound transducer or stationary array transducer (173), and communication wires within the sheath (not shown but must inherently be present) for electrical communication with the transducers for electrical activation and echo reception). (Claims 1, 3, 13).

In the Fig. 8a-b case plural waveguide and redirecting bends are used. (Claim 2).

An optical source as well as detector is inherent in the statements that both transmitting and receiving optical fibers are used, see para [0109] end-portion and that infrared thermographic measurement of the result is made. (Claims 4, 7 - 9).

First and second waveguides and radial redirecting bends are present in Figs.8a, 8b optical fiber elements 187 and are co-located along the longitudinal axis of the catheter in order to view a common pathology site. (Claims 5 – 6, 10, 18).

In the Fig. 7 embodiment for example the distal region of the redirecting bend is rigidly fixed with respect to the adjacent transducer whereas the proximal portion of the bend is becoming flexible by virtue of being more remote from the common attachment point. (Claims 16 – 17).

The fiber and transducer locations can be interspersed at the same longitudinal position or at adjacent but differing longitudinal positions, see the language within paras [0113] and [0114] of Cespedas et al. (Claims 18 – 19).

In the Fig. 7 embodiment the optical fiber and the transducer wire are commonly housed in the rotating transducer drive cable. (Claim 20).

In both Figs. 8a and 8b the optic cables 187 and their redirecting bends as well as the ultrasound annular array 173 are circumferentially disposed about the sheath. (Claim 21).

Claims 11 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cespedes et al as applied to claim 5 above, and further in view of Adler. Whereas the former limitedly uses a reflector element 531, it would have been obvious in view of the latter as discussed above to use either a reflection surface or a prism in lieu of fiber bending in order to re-direct the light beam. (Claims 11 – 12).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cespedes et al as applied to claim 5 above and which is silent as to ultrasound transducer material specifics, and further in view of Melcher, as the latter was applied in the Casscells et al – based rejection of this claim supra. (Claim 14).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cespedes et al as applied to claim 5 above, and further in view of Casscells et al ('075). Whereas the former is silent as to sheath transparency, it would have been obvious in

view of the latter to use such a sheath 40 since this allows that the infrared transmitting fiber does not have to proximate the artery wall where the vessel is tortuous. (Claim 15).

Hence under this rejection section IV the Examiner is applying both the Casscells et al technology nexus and the more recent Cespedas et al technology as separately originating but closely related combined infra-red fiberoptic/ultrasound vulnerable plaque characterizing catheter systems.

US5924997 to Campbell is cited to complete the record since Cespedas et al mentions this patent as combining ultrasound and thermal plaque detection.

Similarly Tearney et al (US6134003) is cited as an OCT-type probe contemplated by Cespedas et al as extending from the workport of their catheter system, see paras [0007] and [0042] final five lines. Tang et al (US6701181) is cited as of interest in showing circumferential fibers and re-directing means in an IR plaque characterizing catheter.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

FJJ:fjj

10-29-2004



Francis J. Jaworski
Primary Examiner